REMARKS

This Reply Under 37 C.F.R. § 1.121 to the Notice of Non-Responsive Amendment (the "Reply") is submitted in response to the Notice of Non-Responsive Amendment dated January 28, 2008 (the "Notice"). By this Reply, as outlined above, Applicants add new claim 58. Following entry of this Reply, claims 1-58 remain pending in the application.

As noted in the Notice, although Applicants' Reply Under 37 C.F.R. § 1.121 to the Notice of Non-Responsive Amendment filed October 30, 2007 included:

(1) an election of Group II, (claims 24-40), drawn to a method of treating pain comprising topically administering to the skin of a mammal in need thereof an emulsion comprising an antidepressant, an NMDA receptor antagonist, a lipophilic component, water and a surfactant; and

(2) an election of the species: (i) amitripyline as the antidepressant; (ii) ketamine as the NMDA receptor antagonist; (iii) petrolatum as the lipophilic component; (iv) PEG-100 as the surfactant; (v) ethoxydiglycol as the lipophilic intradermal penetration enhancer; (vi) sorbitol as the humectant; and (vii) simethicone as the antifoaming agent

that response was found to be non-compliant because:

(a) the specification does not contain adequate written support for Applicants' election of "PEG-100" per se as the surfactant and thus, raises an issue under the provisions of 35 U.S.C. § 112, first paragraph; and

(b) although Applicants elected a particular species of humectant and antifoaming agent, Applicants' elected invention of claims 24-40 does not provide for the use elect a such species as components of the claimed composition.

The above-discussed issues are corrected by the response provided below.

RESPONSE TO RESTRICTION REQUIREMENT

The Examiner required a restriction under 35 U.S.C. § 121, to one of three allegedly distinct invention. Specifically, the Examiner required Applicants to elect one of the following groups of claims for examination on the merits:

I. Claims 1-23, drawn to an emulsion or patch comprising an emulsion comprising an antidepressant, an NMDA receptor antagonist, a lipophilic component, water and a surfactant; classified in class 424, subclasses 401, 443 or 449, for example.

II. Claims 24-40, drawn to a method of treating pain comprising topically administering to the skin of a mammal in need thereof an emulsion comprising an antidepressant, an NMDA receptor antagonist, a lipophilic component, water and a surfactant; classified in class 424, subclasses 401, 443 or 449, for example.

III. Claims 41-57, drawn to a method for inducing local anesthesia, comprising topically administering to the skin of a mammal in need thereof an emulsion comprising an antidepressant, an NMDA receptor antagonist, a lipophilic component, water and a surfactant; classified in class 424, subclasses 401, 443 or 449, for example.

In response, Applicants respectfully traverse the restriction requirement and submit that, for the reasons provided below, the Examiner's restriction of the claims into Groups I, II, and III is improper.

The claims of Groups I , II, and III are directed toward compositions, patches comprising said compositions, and methods involving the use of said compositions and patches. Applicants submit that it a search of the subject matter of these three Groups would

not be a serious burden on the Examiner. Indeed M.P.E.P. § 803 (Rev. 6, September 2007) provides:

> If the search and examination of all the claims in an application can be made without serious burden, the examiner must examine them on the merits, even though they include claims to independent or distinct inventions.

Applicants respectfully submit that it would not be a serous burden for the Examiner to search the subject matter of Groups I, II, and III. Applicants respectfully submit that a search of the literature regarding the invention of Group II will, in fact, encompass the subject matter of Groups I and III as well. Accordingly, on this basis alone, Applicants respectfully request that the restriction requirement imposed under 35 U.S.C. § 121 be withdrawn and the subject matter of pending claims 1-58, be examined in one application.

Notwithstanding the above, in order to be fully compliant to the outstanding restriction requirement, Applicants hereby provisionally elect, with traverse, Group II, (claims 24-40 and 58), drawn to a method of treating pain comprising topically administering to the skin of a mammal in need thereof an emulsion comprising an antidepressant, an NMDA receptor antagonist, a lipophilic component, water, a surfactant, a humectant, and an antifoaming agent.

The Examiner has also required Applicants to elect a species of: (i) an antidepressant; (ii) an NMDA receptor antagonist; (iii) a lipophilic component; and (iv) a surfactant. As required by the Examiner, Applicants hereby elect the following species:

(i) amitriptyline as the antidepressant (as recited in claim 31, as-filed);

(ii) ketamine as the NMDA receptor antagonist (as recited in claim 36, as-filed):

(iii) petrolatum as the lipophilic component (as recited in claim 16, as-filed, and at page 17, line 28 of the specification as-filed); and

(iv) PEG-100 stearate as the surfactant (as recited at page 19, lines 13-16, and in Tables 1 and 2 at pages 31 and 33, respectively, of the application as-filed).

The Restriction Requirement further provided that if Applicants elect an emulsion that further comprises a lipophilic intradermal penetration enhancer, then a further election of a single disclosed species of lipophilic intradermal penetration is required.

In response, Applicants note that the recited emulsion may further comprise a lipophilic intradermal penetration enhancer. Accordingly, Applicants hereby elect transcutol P ® (Gattefossé (ethoxydiglycol)) as a single disclosed species of lipophilic intradermal penetration enhancer (page 21, line 15 of the application as-filed).

The Restriction Requirement further provided that if Applicants elect an emulsion that further comprises a humectant, then a further election of a single disclosed species of humectant is required.

In response, Applicants note that, as recited in new claim 58, the recited emulsion may further comprise a humectant. Accordingly, Applicants hereby elect sorbitol as a single disclosed species of humectant (page 20, lines 28-31 of the application as-filed).

The Restriction Requirement further provided that if Applicants elect an emulsion that further comprises an antifoaming agent, then a further election of a single disclosed species of antifoaming agent is required.

In response, Applicants note that, as recited in new claim 58, the recited emulsion may further comprise an antifoaming agent. Accordingly, Applicants hereby elect simethicone as a single disclosed species of antifoaming agent (page 20, lines 19-20 of the application as-filed).

Claims 24-40 and 58 of elected Group II read on each of the above-elected species of: (i) an antidepressant; (ii) an NMDA receptor antagonist; (iii) a lipophilic component; (iv) a surfactant; (v) a lipophilic intradermal penetration enhancer; (vi) a humectant; and (vii) an antifoaming agent.

Applicants reserve the right to petition from the restriction requirement under 37 C.F.R. § 1.144. Applicants further reserve their right to file one or more divisional, continuation, or continuation-in-part applications directed to the subject matter recited by the

non-elected claims, as well as to any other material disclosed in the specification that is not encompassed by the elected claims.

CONCLUSION

Applicants respectfully request that the above elections and remarks be entered and made of record in the file history of the instant application. No fee is believed to be due for this submission. However, should any fees be required for this submission or to avoid abandonment of this application, please charge such fees to Jones Day Deposit Account No. 50-3013.

Respectfully submitted,

Date: April 28, 2008

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